

APPENDIX B: WAIVERS AND EXEMPTIONS

PDUFA directed FDA to waive or reduce fees in five different circumstances:

- when a waiver is necessary to protect the public health;
- when a fee is a significant barrier to innovation;
- when the fees paid exceed FDA's costs of reviewing a firm's prescription drug applications;
- when imposition of the fee creates an inequity between certain 505(b)(1) and 505(b)(2) prescription drug applications (this waiver provision was deleted in PDUFA III); and
- when a sponsor withdraws a pending prescription drug application after FDA has filed it, but before FDA has performed substantial work on the marketing application.

Beginning in FY 1998, PDUFA II also provided a waiver, for certain small businesses, of the full application fee for the first application submitted.

In addition, under PDUFA II, new exemptions from application fees were added beginning in FY 1998. These specific exemptions are automatic and do not require a waiver request.

They include:

- prescription drug applications for designated orphan products (designated for rare diseases or conditions affecting fewer than 200,000 patients in the United States); and
- supplemental applications for pediatric indications for use (statutorily repealed by section 5 of Public Law 107-109, effective January 4, 2002).

The increased number of exemptions required by PDUFA II reduced the number of applications that require the payment of fees. Fees may be waived or reduced under the waiver provisions of the statute. Many of the application fee waiver requests FDA received through FY 1997 pertained to orphan products; since designated orphan products are now given automatic exemptions, the number of waiver requests for application fees has decreased substantially.

Beginning in FY 2008, PDUFA IV provided exemptions for product fees and establishment fees for certain approved orphan products (see 21 USC 379h(k)).

Table 11 summarizes the waivers and exemptions granted by FDA for PDUFA fees payable in the ten most recent fiscal years, and Table 12 summarizes the amount of fee revenue lost to major exemptions or waiver categories by dollar amount and full application equivalents (FAE).

TABLE 11: EXEMPTION AND WAIVERS AS OF SEPTEMBER 30, 2013

Exempted Application Fees ¹	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
Orphan Product	19.5	28.5	23.8	21.3	27.8	23.8	21.8	33.0	36.6	34.6
Previously Submitted	8.0	3.5	6.0	4.5	4.0	7.5	4.0	5.0	0.0	0.0
Total Exemptions	27.5	32.0	29.8	25.8	31.8	31.3	25.8	38.0	36.6	34.6
TOTAL Value of Exemptions	\$15,771,250	\$21,504,000	\$22,830,150	\$23,077,150	\$37,401,500	\$38,975,000	\$36,191,625	\$58,596,000	\$67,306,825	\$67,823,450

Exempted Orphan Product and Establishment Fees (new in FY 2008)	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
Orphan Product Fee Exemptions	14	16	28	33	30	41
Value of Product Fee Exemptions	\$910,420	\$1,144,320	\$2,232,160	\$2,855,160	\$2,969,100	\$4,033,580
Orphan Establishment Fee Exemptions	5.24	7.45	11.49	16.04	12.14	16.22
Value of Establishment Fee Exemptions	\$2,056,963	\$3,169,869	\$5,252,314	\$7,976,082	\$6,311,414	\$8,538,953
Total Product and Establishment Fee Exemptions	\$2,967,383	\$4,314,189	\$7,484,474	\$10,831,242	\$9,280,514	\$12,572,533

Source: Periodic waiver and exemption data maintained by the CDER Office of Management and fee-exceed-cost waiver data maintained by the Office of Financial Management

¹ Actual number of Exempted Applications received in full fee equivalents

Waived Fees	FY 2004	FY 2005	FY 2006	FY 2007	FY 2008	FY 2009	FY 2010	FY 2011	FY 2012	FY 2013
APPLICATIONS¹										
Small Business Waivers	17.3	12.0	11.0	14.0	26.0	17.0	21.4	16.5	17.0	11.5
Miscellaneous Waivers (Includes PEPFAR) ²	1.0	12.0	13.0	14.0	21.0	10.0	13.1	8.5	5.0	8.5
Value of Waivers Approved	\$10,466,375	\$16,128,000	\$18,417,600	\$25,093,600	\$55,366,000	\$33,674,400	\$48,520,696	\$38,550,000	\$40,513,000	\$39,176,000
PRODUCTS										
Waivers Approved	54.5	32.0	22.0	25.8	17.10180	20.89545	15.87816	29.37747	4.00000	7.0
Value of Waivers Approved	\$1,965,278	\$1,334,720	\$926,860	\$1,283,844	\$1,112,130	\$1,494,443	\$1,265,807	\$2,541,739	\$395,880	\$688,660
ESTABLISHMENTS										
Waivers Approved	22.5	17.0	12.2	13.1	7.8	2.9	5.7	4.7	1.3	1.6
Value of Waivers Approved	\$5,103,000	\$4,453,991	\$3,223,704	\$4,095,372	\$3,053,420	\$1,215,818	\$2,621,489	\$2,345,858	\$691,733	\$848,250
TOTAL Value of Waivers Granted	\$17,534,653	\$21,916,711	\$22,568,164	\$30,472,816	\$59,531,550	\$36,384,660	\$52,407,992	\$43,437,597	\$41,600,613	\$40,712,910
GRAND TOTAL – Exemptions & Waivers	\$33,305,903	\$43,420,711	\$45,398,314	\$53,549,966	\$99,900,433	\$79,673,849	\$96,084,091	\$112,864,839	\$118,187,952	\$121,108,893

¹ Actual number of Application Fee Waivers Granted-number of waived applications actually received may vary.

² PEPFAR refers to applications for drugs to treat HIV/AIDS excluded from fees under the President's Emergency Plan for AIDS relief.

TABLE 12: DOLLAR VALUE OF MAJOR EXEMPTION AND WAIVER CATEGORIES FOR EACH FISCAL YEAR

Fiscal Year	Exempt Orphan Application Fees		Small Business Application Fees		PEPFAR & Miscellaneous Application Fees	
	Dollar Value	# in FAE	Dollar Value	# in FAE	Dollar Value	# in FAE
2004	\$11,183,250	19.500	\$9,892,875	17.250	\$573,500	1.000
2005	\$19,152,000	28.500	\$8,064,000	12.000	\$8,064,000	12.000
2006	\$18,225,750	23.750	\$8,441,400	11.000	\$9,976,200	13.000
2007	\$19,044,250	21.250	\$12,546,800	14.000	\$12,546,800	14.000
2008	\$32,689,500	27.750	\$30,628,000	26.000	\$24,738,000	21.000
2009	\$29,621,000	23.750	\$21,202,400	17.000	\$12,472,000	10.000
2010	\$30,569,625	21.750	\$30,042,563	21.3750	\$18,476,408	13.146
2011	\$50,886,000	33.000	\$25,443,000	16.500	\$13,107,000	8.500
2012	\$67,306,825	36.550	\$31,305,500	17.000	\$9,207,500	5.000
2013	\$67,823,450	34.625	\$22,526,200	11.500	\$16,649,800	8.500
Total	\$346,501,650	270.425	\$200,092,738	163.625	\$125,811,208	106.146

Fiscal Year	Exempt Orphan Establishment Fees -- Began in FY 2008		Exempt Orphan Product Fees Began in FY 2008	
	Dollar Value	# in Full Est. Fees	Dollar Value	# in Full Product Fees
2008	\$2,056,963	5.238	\$910,420	14.000
2009	\$3,169,869	7.448	\$1,144,320	16.000
2010	\$5,252,314	11.488	\$2,232,160	28.000
2011	\$7,976,082	16.042	\$2,855,160	33.000
2012	\$6,311,414	12.135	\$2,969,100	30.000
2013	\$8,538,953	16.218	\$4,033,580	41.000
Total	\$33,305,595	68.569	\$14,144,740	162